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10/689,081	10/21/2003	Aime Flesch	P08024US00/RFH	2820

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EXAMINER
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JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/689,081

Applicant(s)

FLESCHE ET AL.

Examiner

Jaworski Francis J.

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 2-24-2004(IDS).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 - 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 - 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 02242004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

Claims 1 - 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Base claims 1 and 11 refer to a “unique” footprint which is a subjective term different in scope from a common or fully overlapping footprint and creates an indefiniteness as discussed further below.

2) More importantly base claims 1 and 11 refer to “ a first sub-array of transducers disposed on a first surface of the piezoelectric member and a second sub-array of transducers disposed on a second surface of the piezoelectric member.. “. In ultrasound since a ‘transducer’ which may be a single element or a linear or a matrix array of such elements ordinarily consists of energizing electrodes on two surfaces and a piezoelectric element sandwiched between the surfaces such that the electrodes supply a voltage to the element(s) so as to cause a pressure wave by voltage-to-pressure transduction during transmission and receive a voltage signal due to pressure-to-voltage transduction of the echo returning from the investigated body, any definition of transducer necessarily includes the ‘piezoelectric member’ and therefore ‘first and second sub-arrays of transducers’ cannot be claimed as being disposed on surfaces of the piezoelectric member because they are not distinct from this member, in terms of what applicants are disclosing.

Additionally there are ultrasound transducer types which are true multi-layer and therefore comprise transducer sub-arrays disposed on piezoelectric members. Gururaja (US5410205) represents a multi-layer transducer adapted to resonate at different frequencies dependent upon the polarities applied to the respective layers; Gururaja (US5625149) pertains to a multi-layer transducer for the different purpose of optimizing mechanical acoustic impedance match on the pressure wave side and electrical impedance match on the circuit side.

Additionally there are six categories of transducer arrangements which the artisan and (the Examiner believes) the applicants would agree are characterizable as biplanar at 90 degree offset and with a unique and/or common footprint and involve both transducer surfaces in each mode but conflict with the awkwardness of the base claims' language:

**I. Biplanar transducer via piezoelectric and electrode adaptations; common footprint** – (Shaulov et al 1988 IEE Symp. or US4671293 of record on specification page 8)) - Array is partially cross-diced at 90 degrees to partial dicing on opposite surface together with perpendicularly oriented electrodes on opposing surfaces. Footprint (emission face area location) is identical in both scan modes.

**II. Biplanar transducer via piezoelectric and electrode adaptations; overlapping but not common footprint** - (ShaulovUS4870867) – Array is diced and cross-diced as above; electrodes are cross-oriented on opposing

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transducer faces as above. Footprint is overlapping but non-identical in the two scan modes.

**III. Biplanar transducer via 2-surface electrode adaptations; common**

**footprint** – (t'Hoen US4640291 of record on page 8 of the specification; Hashimoto et al US5327895) - t'Hoen piezoelectric is in a generic x-y matrix (that is, non-specific to biplanarity) of block or cube elements separated by segmented spacers; Hashimoto et al piezoelectric is in a generic matrix of cylindrical pillars or rods distributed in an inert binding material. Footprint is identical in both scan modes

**IV. Biplanar transducer via single-surface electrode adaptations,**

**overlapping but not common footprint** - (Slayton et al US5103129 of record on page 9 of the specification) – linear and matrix array hybrid with single-surface electrode adaptations to achieve biplanarity; Footprint is overlapping but non-identical in both scan modes.

**V. Biplanar transducer by virtue of external connections, overlapping but**

**not common footprint** – (Smith et al US6641534) 'Ordinary' piezoelectric cross-diced elements and overlying island electrodes serve to form a biplanar-acting array by virtue of connections external to the transducer which serve to electrically create the sub-aperture groupings.

**VI Biplanar transducer by virtue of external connections, overlapping and may include common footprint** (Friemel et al US6537220) see Figs. 6 – 7 and cols. 1 – 2 bridging passage.

i) Each such transducer is biplanar; either by adaptations of the transducer piezoelectric and/or electrodes or by the interconnection of the transmission/reception circuits which act to form the sub-array for the individual scan plane and ii) the biplanarity is at a 90 degree offset and iii) each such transducer has a unique footprint having at least a partly common portion, and iv) each such transducer functions in each scan mode such that it involves both transducer array surfaces because both electrodes provide the signal path. The Examiner is adopting this paragraph's features i) – iv) as a definition of what is being claimed in lines 3 – 10 of the base claim 1.

Additionally claim 7 insofar as it describes a rotational relationship between the second bi-plane array and itself is vague and indefinite, see specification para [0107] and Figure 15 relating thereto.

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

[ Parenthesized claim numbers identify the specific claim or claims towards which the immediately preceding rejection statement is directed. ]

Claim 1 is rejected under 35 U.S.C. 102(b) (or 102(e) in the case of Smith et al, Friemel et al) as being anticipated by

any one of the above-cited patents in the alternative, where the applicability against claim 1 lines 3 – 10 is as stated above regarding I) – iv) for each case, and:

Shaulov '293 - col. 4 line 40; col. 5 line 8 indicate that the Mylar matching layer and mechanical lens would serve as a 'tip' overlying the transducer; 'invasive application' use accorded no patentable weight.

Shaulov '867 - spherical lens (col. 3 lines 29-40 is tip; 'invasive application' is needle biopsy.

t'Hoen - spherical lens (cols. 3-4, bridging) is tip; 'invasive' accorded no patentable weight.

Hashimoto et al – transesophageal or rectal ultrasound probe (col. 1 lines 33 – 53) must have covering tip to function otherwise several hundred volts energizing the array would transfer to interior of the patient; TEE and rectal case are invasive per specification definition paras [0032, 0035].

Slayton et al - tip at 11 of Fig. 1a; invasive per applicants' definition since endorectal/endovaginal see col. 1 lines 22-25.

Smith et al – has tip/ is invasive since mounted to endoscope, catheter, see col. 7 lines 10 – 12.



Friemel – tip mechanical lens see col. 2 bottom; ‘invasive application’ intended use accorded no patentable weight.

Claims 1, 8, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossack et al (US6014473, of record on page 6 of the specification) in view of Hossack et al (US6364835), further in view of either Shaulov (IEEE Symp. 1988) or Hashimoto et al, as mentioned in col. 18 lines 20 – 24 of Hossack et al.

Specifically Hossack et al teaches use of a biplanar TEE probe array in col. 6 lines 15 – 18 and invokes biplanar array use specifically as in Shaulov et al and Hashimoto et al, see col. 18 lines 20 – 45 but is equivocal as to whether an invasive probe structure is used for this system. However it would have been obvious in view of the later Hossack et al to incorporate into a catheter system as per Fig. 7 therein since the later Hossack et al invokes the former in the course of extending this combined tracking and imaging technology. Either the imaging or the tracking functions are applications in association with the invasive probe catheter (Claim 1).

At least some of the Fig. 23 – 26 embodiments use both a linear array and biplanar array portions whose acoustic patterns intersect (Claims 8, 11).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hossack et al (‘473) in view of Hossack et al (‘835), further in view of Shaulov et al or Hashimoto et al as applied to claim 1 above, and further in view of Hossack

et al (US5680863) since whereas the former are silent as to bendable articulation points, the latter indicates that such are conventional proximal to the transducer in an invasive device, see col. 6 lines 49 – 54. (Claim 2).

Claims 3 - 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Hossack et al-based reference group as applied to claim 1 supra,, and further in view of Slayton et al. Whereas the former are silent as to the transducer having a curved shape, Slayton et al in Fig. 1a, 4 and Fig. 9b teach that such can be achieved in their design thereby facilitating an overall invasive probe, see col. 1 lines 50 – 55. (Claims 3-4).

Although the former references are silent as to catheter-based orientations, the design in Slayton et al specifically orients the biplane transducer so that one plane is oriented longitudinally and the acoustic propagation axis  $r$  is perpendicular thereto. (Claim 5).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Hossack et al – based reference group as applied to claim 1 above, and further in view of Hossack et al (US6045508) since whereas the former are silent as to angulated array use, it would have been obvious in view of the latter Figs. 7- 10 to provide same in order to extend viewing versatility. (Claim 6)..

Claims 9 – 10, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Hossack et al-based rejection group as applied to claim 1 above, and further in view of Shaulov ('867) and Hossack et al '863 since whereas the former are silent as to biopsy guide use with a biplanar array it

would have been obvious in view of the latter Shaulov col. 3 lines 23 – 28 to incorporate a biopsy needle guide so that the biplanar array can guide biopsy along two orthogonal planes. (Claim 9)..

Hossack et al '863 in Figs. 29 - 30 would then teach that the biopsy needle should be co-located with and extend into the field of view of the ultrasound array positioned in one direction along the longitudinal axis. (Claims 10, 13).

Claim 15 is rejected under 35 U.S.C. 102(b, e) as being anticipated by Slayton et al. The former teaches in Fig. 1a and col. 1 lines 53 – 55 and Fig. 14 elements 82 and 88 an invasive biplane imaging probe whose first and second sub-arrays are controlled by multiplex switching. (Claim 15).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slayton et al as applied to claim 15 above, and further in view of Smith et al . Whereas Smith et al discuss selecting the subapertures on their system, this is effectively a switching and col. 4 lines 18 – 46 make clear that the programmed selections are under software control. (Claim 16).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slayton et al as applied to claim 15 above, and further in view of Oaks et al (US5050610). Whereas the former is silent as to specific switching controls, it would have been obvious in view of the latter to position same on the probe handle to facilitate versatility of operation local to the probe manipulation site. (Claim 17).


***Allowable Subject Matter***

Claims 7, 12, 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 703-308-3061.

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Francis J. Jaworski  
Primary Examiner